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Treatment of Early Post-Op Wound Infection after Internal Fixation

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14. ABSTRACT Postoperative infection is one of the most prevalent and challenging complications faced by orthopaedic surgeons and patients in both the military and civilian populations. The wounds are contaminated or colonized at the time of injury, during the course of therapy, or both. Infection is always a possibility with any surgical intervention, particularly in the setting of orthopaedic trauma where multiple factors make the prevention and treatment of these infections very complicated. Due to the difficulties we have had with randomization, we felt that it was critical to establish the external validity of the results in an observational cohort. The observational amendment was approved by the Johns Hopkins School of Public Health IRB on July 9, 2014 and we received acknowledgment of this amendment from the DoD on September 18, 2014. The sites are in the process of obtaining approval of the observational amendment locally. We have initiated training calls between the study PI, coordinating center and individual sites. The purpose of these calls is to assist the sites which issues regarding recruitment, enrollment and study conduct. During the past year we received feedback from the sites that some physicians were having difficulty maintaining equipoise when prescribing antibiotics. Informational slides have been developed for the sites to use to present the study to their Infectious Disease teams to assist with this problem.					
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**Annual Report: “Treatment of Early Post-Op Wound Infection after Internal Fixation”  
Sept. 15, 2013 - Sept. 14, 2014**

**Introduction:**

Severe fractures are common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation develop a deep wound infection during the healing process. Thus, the overall goals of this study are to (1) evaluate the effect of treatment of post-op wound infection in long bones after fracture fixation or joint fusion and either: (Group 1) operative debridement and PO antibiotic treatment for 6 weeks; or (Group 2) operative debridement and IV antibiotics for 6 weeks and (2) build and validate a risk prediction model for failure of treatment of early postoperative wound infections after fixation of fractures or joint fusion.

**Body:**

During the current reporting period, the Principal Investigator (PI) focused on administrative tasks essential to recruitment and enrollment into the study. Due to the difficulties we have had with randomization, we felt that it was critical to establish the external validity of the results in an observational cohort. The observational amendment was approved by the Johns Hopkins School of Public Health IRB on July 9, 2014 and we received acknowledgment of this amendment from the DoD on September 18, 2014. The sites are in the process of obtaining approval of the observational amendment locally.

We have initiated training calls between the study PI, coordinating center and individual sites. The purpose of these calls is to assist the sites which issues regarding recruitment, enrollment and study conduct.

Currently, there are 24 centers participating in this study (14 are certified). 309 patients have been screened for eligibility and of these, 102 (33%) were eligible at the time of consent. We consented and enrolled 45 patients (44% of eligible). Five patients have completed the study.

Task 1	Months 1-6	Completed
Task 2	Months 2-6	Completed
Task 3	Months 7-30	Roll out of enrollment – in progress
Task 4	Months 7-42	Enrollment ongoing
Task 5	Months 43-48	initiated

*Problem Areas:*

During the past year we received feedback from the sites that some physicians were having difficulty maintaining equipoise when prescribing antibiotics. Informational slides have been developed for the sites to use to present the study to their Infectious Disease teams to assist with this problem.

*Next Steps:*

- Assist sites with facilitation of the observational amendment approval at local IRBs
- Encourage sites to schedule meetings Infectious Disease teams to review study and study roles
- Develop Reports related to project deliverables for Consortium

**Key Research Accomplishments:**

- DoD approval of the Observational amendment and dissemination to the sites
- Five patients have completed the study
- Increased rate of enrollment

**Reportable Outcomes:**

None

**Conclusion:**

None

**References:**

None

**Appendices:**

None